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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,738	12/08/2000	William Peter Van Antwerp	G&C 130.9-US-U1	4789

22462 7590 08/13/2002

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EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1653

DATE MAILED: 08/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/733,738

Applicant(s)  
Van Antwerp

Examiner  
David Lukton

Art Unit  
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 12, 2001
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-24 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1-3, drawn to compositions in which a "phenolic preservative" is absent.
2. Claims 1-12, 17, drawn to compositions in which a "phenolic preservative" is present.
3. Claim 18, drawn to a method of making a composition
4. Claims 19-24, drawn to a method of stabilizing a polypeptide.

Inventions 2 and 1 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed. First, neither Group 1 nor Group 2 requires the inclusion of insulin; there are vast numbers of biologically active peptides which are biologically active and useful in the absence of phenol. Second, even if Groups 1 and 2 mandated the presence of insulin, the fact is that insulin can be used effectively without phenol.

Inventions 3 and 2 are related as process of making and product made. The inventions are

distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). First, Group 2 is not limited to insulin, whereas Group 3 is; second, while Group 3 currently describes a random mixing process, it may later be amended to describe a more specific order of mixing, or additional process steps which would require a further search. Nevertheless, in the event that (a) Group 2 is elected, (b) the polypeptide species is insulin and (c), the claims are found allowable, Group 3 will be rejoined therewith for further examination.

Groups 4 and 2 are neither related as process of making and product made nor as product and process of use. In the event that Group 2 is elected, there will be no requirement to rejoin Group 4. Nevertheless, in the event that Group 2 is elected, and claims therein found allowable, the issue of rejoining Group 4 may be revisited.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

\*

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect various species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable:

- (a) a specific peptide such as Asp B28 human insulin, Ser17- human *beta*-interferon, or bovine interleukin-2;

- (b) a specific "buffering molecule" which absorbs CO<sub>2</sub> but which lacks a free amine group
- (c) zinc is present, or zinc is absent
- (d) an isotonicity agent is present or an isotonicity agent is absent; if present, what is the specific agent?
- (e) in the event that Group 1 is not chosen for examination, an election of a specific phenol is required (e.g., phenol *per se*, C<sub>6</sub>H<sub>5</sub>OH);

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention. Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800